

REMARKS

Applicants would like to thank Examiner Lacyk for the courtesy extended in the telephone interview conducted on September 5, 2001. Claims 1-17, 19-21, 23-25, and 28-40 are currently pending.

As discussed in the telephone interview, enclosed herewith is a copy of a declaration of the inventor Robert Hess under 37 C.F.R. 1.131 executed on December 6, 1992 and previously filed in the parent application, serial number 07/755,480. Also enclosed is a Supplement Reissue Declaration as required in the Office Action.

In the Office Action, the Examiner has indicated that the Amendment filed December 8, 2000 is improper because the specification does not include underlining of the additions and the new claims lack the proper underlining. The foregoing amendments have been submitted in the proper format including underlining of the added subject matter in the specification and underlining of all the new claims. For ease of entry of the amendments, all the new pending claims 6-17, 19-21, 23-25, and 28-40 have been reproduced in this Amendment. Claims 1-5 of the original patent have been indicated to be allowed.

Rejection under 35 U.S.C. §102

In the Office Action, Claims 10 and 11 were rejected under 35 U.S.C. §102(b) as being anticipated by Weinstein et al. As discussed in the telephone interview with the Examiner, the Declaration under 37 C.F.R. 1.131 submitted in the parent application, a copy of which is enclosed herewith, establishes a date of invention for the claimed invention prior to the September 6, 1990 earliest filing date of Weinstein et al. Accordingly, the rejection under 35 U.S.C. §102 based on Weinstein et al. should be withdrawn.

In the foregoing amendments, the amendments made to Claims 6, 10, and 17 in the Preliminary Amendment filed on December 5, 2000, have been reversed. These amendments made in the December 5, 2000 Preliminary Amendment were unnecessary since Weinstein et al. is not prior art. The amendments to Claims 19-21, 23, and 24 made in the December 5, 2000 Preliminary Amendment have not been removed because these

amendments were made for purposes of clarification and not for purposes of distinguishing from Weinstein et al.

In addition, Claim 33 has been amended to depend from Claim 23 to provide antecedent basis and the term "cut out" has been amended to "window" for consistency.

Rejection under 35 U.S.C. §112

Claims 10 and 18 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 18 has been canceled in order to expedite prosecution. In addition, the objectionable language "in close proximity" in Claim 10 has been removed by the foregoing Amendment.

New Claims 34-40 have been added in this amendment to further define the protection to which Applicant is entitled. Claims 34-40 are allowable over the prior art for at least the same reasons as Claims 6 and 10.

Finally, Applicants note that the original patent or an affidavit or declaration as to loss or inaccessibility of the original patent must be received before this reissue application can be allowed. The original patent is believed to have been lost. Two Declarations as to Loss or Inaccessibility are submitted herewith setting forth the facts resulting in the loss.

All outstanding matters in the Office Action are believed to be addressed by the foregoing amendments. In the event that there are any questions concerning this Amendment, or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Cindy A. Lynch
Cindy A. Lynch
Registration No. 38,699

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650)622-2300

Date: October 10, 2001



PATENT
Attorney Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Robert L. HESS

Serial No.: 07/755,480

Filed: September 5, 1991

For: **METHOD AND APPARATUS FOR
RESTENOSIS TREATMENT**

Group Art Unit: 3305

Examiner: J. Lacyk

DECLARATION UNDER 37 CFR §1.131

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Robert L. Hess, declare that:

1. I am the inventor of the subject matter claimed in U.S. Patent
Application Serial No. 07/755,480.

2. Exhibit A attached hereto discloses a method for treatment and post-treatment of the stenosed region of an artery. The method includes steps of reducing the annular stenosed area within an artery and advancing a radioactive dose means within the artery to the area of reduced stenosis. The radioactive dose means is operatively connected to positioning means and the advancing step is performed by moving the positioning means. The method also includes steps of applying a radioactive dose to the area of reduced stenosis by exposing the area of reduced stenosis to the radioactive dose means and removing the dose means from the artery by moving the positioning means. Exhibit A also discloses apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other means. The apparatus includes radioactive dose

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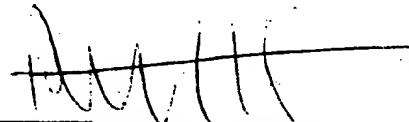
means and positioning means operatively connected to the dose means for advancing the dose means and positioning the dose means within the stenosed region of an artery that has been reduced by angioplasty or other means. The positioning means is also operatively connected to the dose means for withdrawing the dose means from the artery. Exhibit A was prepared in the United States prior to December 11, 1989.

3. Work performed by me or under my direction relating to guide wires and catheters for use with radioactive dose means to be used for treatment and post-treatment of the stenosed region of an artery has been ongoing in the United States from prior to December 11, 1989 through the September 5, 1991 filing date of U.S. Patent Application Serial No. 07/755,480.

The undersigned inventor declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

6 Dec 1992

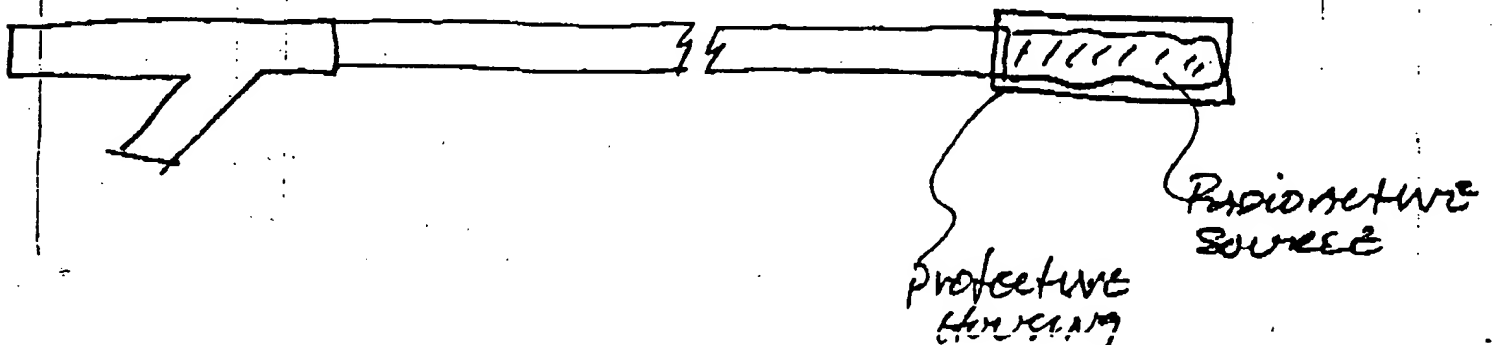
Date



Robert L. Hess

EXHIBIT A

ATHEROSCLEROSIS, HOT BALLOONS (LASER: OTHERS) AND THE USE OF STENTS HAVE BEEN THOUGHT TO POTENTIALLY HAVE SOME VALUE IN REDUCING RESTENOSIS RATES. HOWEVER, THE DATA WHICH IS NOW COMING IN SEEMS TO INDICATE THAT THESE METHODS DO NOT SIGNIFICANTLY REDUCE RESTENOSIS RATES. IN RESTENOSIS A PROLIFERATION OF CELLS FOLLOWING ANGIOPLASTY OR ATHERECTOMY CAUSES THE LESION TO REFORM - THE RATE OF RESTENOSIS IS GENERALLY CONSIDERED TO BE ABOUT 33%. THEREFORE IT WOULD BE DESIRABLE TO HAVE A MEANS AND A METHOD TO TREAT LESIONS WITH A REDUCED RESTENOSIS RATE - I PROPOSE A CATHETER WHICH HAS, AT ITS DISTAL END, A RADIO ACTIVE SOURCE. THE SOURCE WOULD BE MANEUVERED TO THE SITE OF A LESION WHICH HAS BEEN DILATED OR REMOVED AND THE SITE WOULD BE EXPOSED TO A RADIATION DOSE THAT WOULD KILL SMOOTH MUSCLE CELLS. IF THIS CAN BE DONE IN A CONTROLLED MANNER, IT IS POSSIBLE THAT THE RAPID GROWTH OF CELLS COULD BE PREVENTED AND RESTENOSIS CONTROLLED.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of

Robert L. HESS

Serial No.: 08/850,073

(Reissue of U.S. Patent No. 5,411,466)

Filed: May 2, 1997

For: APPARATUS FOR RESTENOSIS
TREATMENT



Group Art Unit: 3736

Examiner: J. Lacyk

#17

DECLARATION OF ROBERT L. HESS
AS TO LOSS OR INACCESSIBILITY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Robert L. Hess, hereby declare that:

U.S. Patent No. 5,411,466 was assigned from me to United States Surgical by an assignment dated December 15, 1997;

The Original U.S. Letters Patent No. 5,411,466 was transferred to United States Surgical following the assignment;

I understand that United States Surgical cannot locate the above original letters patent;

I have not been able to locate the above original letters patent and believe that it is lost or inaccessible.

I further declare that all statements made herein of my own knowledge are true and that all statements made no information and belief are believed to be true; and further, that

Application No. 08/850,073
Attorney's Docket No. 011683-012
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these statements were made with the knowledge that willful false statements and the like so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of the application or any patent issuing thereon.

Dated: October 03, 2001

By: 

Robert L. Hess

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of

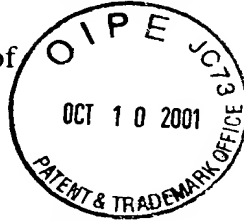
Robert L. HESS

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TREATMENT



Group Art Unit: 3736

Examiner: J. Lacyk

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SUPPLEMENTAL DECLARATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Robert L. Hess, the above-named inventor, hereby declare that:

I am a citizen of the United States, and my residence is 35 Tagus Court, Portola Valley, California, 94028.

I verily believe myself to be the original, first inventor of the invention described and claimed in U.S. Letters Patent No. 5,411,466 (the "'466 patent") and for which invention I have solicit a Reissue Patent.

I have reviewed and understand the contents of the specification and the claims of the Reissue Application. I have also reviewed and understand the contents of the original specification of Serial No. 08/219,179 (U.S. Pat. No. 5,411,466) filed March 28, 1994 as a continuation of Serial No. 07/755,480 (U.S. Pat. No. 5,302,168) filed September 5, 1991. I have also reviewed and understand the amendments to the specification and claims filed herewith.

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I do not know and do not believe that said invention was ever known or used in the United States of America before my invention thereof.

I acknowledge my duty to disclose all information known to me which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

PETITIONER further declares the following:

I verily believe the '466 patent may be at least partly inoperative or invalid for the reason that I claimed less than I had a right to claim in the '466 patent.

Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath or declaration submitted in this application, arose without deceptive intention on my part.

I further declare that all statements made herein of my own knowledge are true and that all statements made no information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of the application or any patent issuing thereon.

Dated: October 03, 2001

By: 

Robert L. Hess